

LaVada Watson
Worldwide Director
Regulatory Affairs
Telephone (770) 431-8952
Telefax (770) 431-5790
Internet lavada_watson@colpal.com

September 17, 2004

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 81N-033P – Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Notice of Eligibility; Request for Data and Information on Triclosan (69 Fed. Reg. No. 128, Page 40640 - 40641, July 6, 2004)

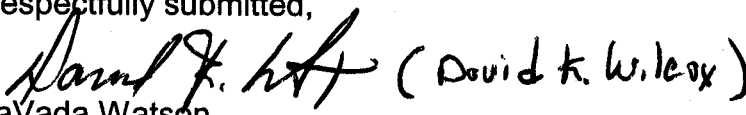
Dear Sir or Madam:

Colgate-Palmolive Company (Colgate-Palmolive) requests a 45 day extension of the deadline to the call for safety and efficacy data concerning Triclosan as an antigingivitis ingredient in dental pastes and oral rinses. The original deadline is October 4, 2004. Colgate-Palmolive requests that this be extended to November 18, 2004.

Colgate-Palmolive requires additional time to evaluate the efficacy data on triclosan-containing dental pastes and oral rinses both in the United States and abroad in the context of the new TEA procedure. By extending the deadline, the FDA will allow Colgate-Palmolive to prepare a comprehensive submission addressing the formula-dependent efficacy of triclosan-containing dental pastes and mouth rinses so this information can be fully evaluated in light of efficacy requirements for antigingivitis/antiplaque drug products in the monograph being developed for OTC oral health care drug products (21 CFR part 356).

Colgate-Palmolive appreciates the Agency's consideration of our request for an extension.

Respectfully submitted,

for  (David K. Wilcox)
LaVada Watson
Worldwide Director
Regulatory Affairs

cc: Robert L. Sherman (HFD-560)